EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGITATION	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO PLAINTIFF: **Diane Bellew (2:12-cv-22473)**	

RULE 26 EXPERT REPORT OF HOWARD JORDI, PhD

I. Background and Qualifications

I, Dr. Howard Jordi received my undergraduate degree in Chemistry from Northern Illinois University in 1967 and my Ph.D. in biochemistry from the same university in 1974.

From 1973-1977, I served in the United States Army Institute of Dental Research where I characterized various drugs contained in biodegradable copolymers of polylactic and polyglycolic acid. I then worked at Water's Associates from 1977-1980. Water's is a world leader in the sale of a wide range of analytical technologies including liquid chromatography, mass spectrometry, rheometry and microcalorimetry. At Waters, I progressed from a Biological Applications chemist to the laboratory manager for the life science division and finally to the Chemicals Applications Manager for the Chromatography Supplies Division.

I am the founder of Jordi Labs and served as president and CEO from 1980-2008. Jordi Labs was founded to provide high quality analytical services to the polymer and plastics industries. In my role as President and CEO, I developed hundreds of analytical methods and have analyzed all of the major polymer systems (polypropylene, polyethylene, urethanes, styrenics, etc.). In this capacity, I have been analyzing polypropylenes for over 25 years. I have deformulated numerous polypropylene samples including identifying and quantifying their additive packages and have been aiding clients for over 25 years in the identification of the root cause of failure in polypropylene systems. I have served extensively as a consultant on polymer related failures for a wide range of industrial clients and have over 40 years of practical experience in the analytical chemistry of polymers. I have in-depth knowledge of a wide range of analytical techniques including FTIR, NMR, DSC, TGA, HPLC, SEM, GPC, DMS, LCMS, GCMS, nanothermal analysis, H-GCMS and PYMS among others. Jordi Labs currently offers over 20 different analytical techniques. I have developed a range of polymeric chromatography columns for polymer molecular weight determination, some of which are patented.

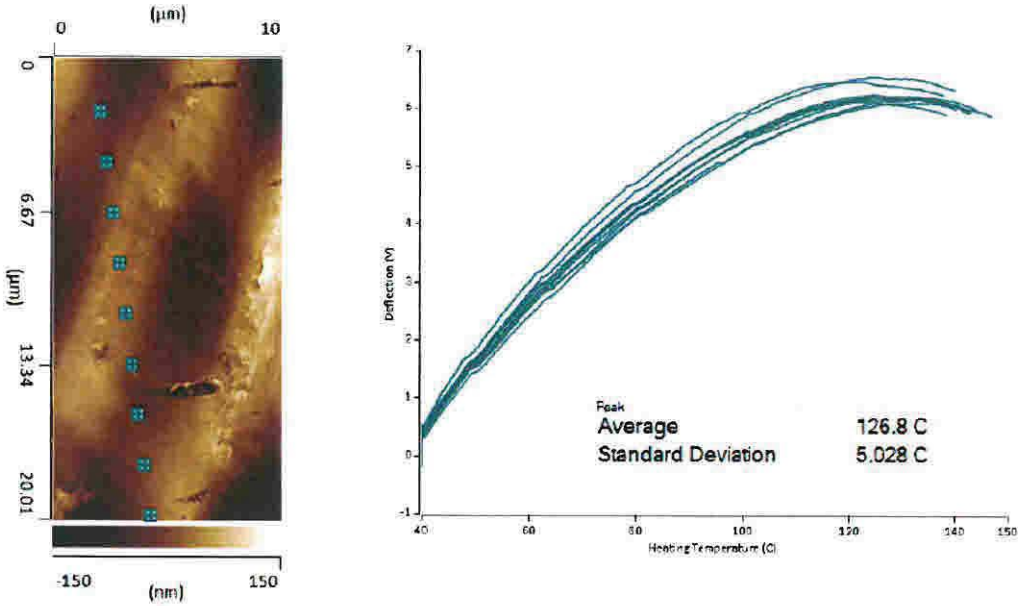

Figure 82 - AFM height image showing surface topography of Bellew, Dianne B fibers in region away from cracks (left). nanoTA measurements obtained away from the cracked regions on Bellew, Dianne B fibers (right).

Bellew, Dianne C (sodium hypochlorite treated)

Bellew, Dianne C treated with hypochlorite were also examined with AFM imaging and nanoTA. As can be seen from the AFM image in **Figure 83** (left), there is a significant difference surface morphology between the Bellew, Dianne B and Bellew, Dianne C fibers with large flakes of material visible on the surface of the hypochlorite treated bellew fibers.

nanoTA measurements **Figure 83** (right) on these flake like materials show an even lower thermal transition than observed for the Bellew, Dianne C on their own (~ 78 °C). When the flaked material was avoided the thermal transitions observed were slightly lower than those of the untreated fibers.

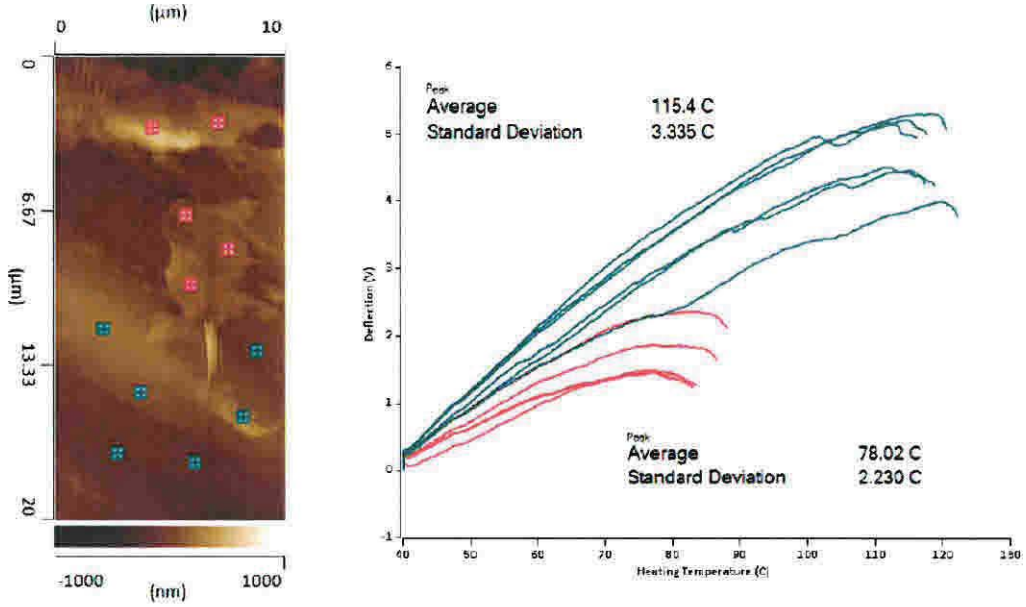

Figure 83 - AFM height image of surface of hypochlorite treated Bellew, Dianne C (left). nanoTA measurements on Bellew, Dianne C both on (red) and off (blue) the flake-like material (right).

Scientific Opinion

Based on the nanothermal analysis data, it is my opinion to a reasonable degree of scientific certainty that the Bellew samples (untreated and hypochlorite treated) show significant surface degradation as compared to the exemplars (prestine, formalin treated and hypochlorite treated). Melt temperature of the polymer decreases with decreasing molecular weight.[100] Since chemical degradation of the polymer also results in decreased molecular weight by mechanisms outlined in section IV (Degradation) of this report, a reduction in the melt temperature is an indicator of chemical degradation as well. In other words, the melt point decreases with a decrease in molecular weight as shown in the literature.[100] In fact, according to Natta et al, isotactic polypropylene with a melt point of ~120-130 °C would indicate that the molecular weight has degraded to below 5000. The non-hypochlorite treated Bellew sample showed melt temperatures of 121 °C in the cracked region and 127 °C in the uncracked region indicating that the explant degraded before cracking occurred on its surface. This is consistent with the SEM-EDX data where increased oxygen levels were observed in the uncracked region of the non-hypochlorite treated Bellew sample. AFM imaging of the hypochlorite treated Bellew sample showed flakes which were not observed in the untreated Bellew sample. The hypochlorite treated Bellew sample showed even lower melt temperatures of 115 °C off the flakes and 78 °C on the flakes.

[100] G. Natta, I. Pasquon, A. Zambelli and G. Gatti "Dependence of the melting point of isotactic polypropylenes on their molecular weight and degree of stereospecificity of different catalytic systems" *Macromol. Chem. Phys.*70 (1964) 191-205.

These temperatures are significantly different from the treated and untreated exemplars that showed a melt temperature of ~176 °C. The vast difference in the melt temperatures of the exemplars and the Bellew sample indicates extreme alteration in the chemistry of the surface of the Bellew fibers. This result is not unprecedented in the literature as it was observed by Ethicon's own studies that temperatures in the range of 147-156 °C are in the "realm of degraded prolene".[101]

The pristine and hypochlorite treated exemplars showed similar melt temperatures suggesting that the sodium hypochlorite treatment had no effect on the exemplar. Sodium hypochlorite is known to be a strong oxidizing agent capable of oxidizing polymers like polypropylene. However, in the presence of antioxidants like DLTDP, polypropylene can withstand the chemical attack by sodium hypochlorite. On the other hand, if the antioxidant is absent, polypropylene undergoes oxidation when exposed to an oxidizing agent. It was determined from the LCMS and PYMS studies that DLTDP, an antioxidant used by Ethicon for the long term stability of the polypropylene mesh, is virtually absent in the Bellew explant making it susceptible to oxidation/degradation. This degradation was evidenced form the nanoTA data by comparing the melt temperatures of the untreated Bellew fibers (121-127 °C) with the hypochlorite treated Bellew fibers (78-115 °C). The data suggests that sodium hypochlorite treatment further degrades the explant sample.

The observed difference in the melt temperatures between the exemplars and the Bellew fibers was greatly enhanced in the nanoTA analysis as compared to that in the DSC analysis. DSC is a bulk technique and gives the melt temperature of the entire volume of the sample analyzed, whereas nanoTA is a surface technique capable of looking at very tiny areas (~nm) on the surface of the fibers. Based on my knowledge, training and experience and previous analysis of the explanted polypropylene meshes, it can be stated to a reasonable degree of scientific certainty that degradation in these fibers is a surface phenomenon initially, which will more likely than not continue deeper and deeper into the fiber as time passes. Thus the surface layer is degraded first and shows a greater difference in the melt temperature compared to the bulk.

VII. My Analysis of other TVT and TVT-O Controls and Explants Provides Additional Support for My Opinions that Prolene Degrades *In Vivo*

In addition to the scientific literature, Ethicon's internal documents and my data from Ms. Bellew's explanted Prolift device, I also analyzed other Prolene devices manufactured by Ethicon which were explanted from 24 other patients. The data from this analysis provides further support for my opinions that Prolene undergoes *in vivo* degradation.

Explant Samples:

[101] ETH.MESH 00000367 Notebook 1918, Page 248.

Just like the Prolift device that was implanted in Ms. Bellew, the TVT and TVT-O devices analyzed from 24 other patients' explants are manufactured using Prolene polypropylene, with the only difference being the fiber size and amount of Prolene used to manufacture the different devices. According to Ethicon documents, the mesh material in the TVT & TVT-O products is Prolene Old Construction 6 mil mesh.[102,103,104] While Prolift is manufactured with a smaller fiber diameter,[105] it is still made with the same Prolene polypropylene material used to manufacture the TVT and TVT-O devices.

The 24 explant samples analyzed by Jordi Labs were selected randomly at Steelgate, the facility which was storing the explants after they were surgically removed by the patients' physicians. Only TVT and TVT-O explants were selected. The protocol further required that only explants with sufficient material for histopathology and degradation analysis would be used. The patients' medical records, including prior pathology reports, were not considered in the selection process.

A. Sample Identification

Control Samples - TVT and TVT-O

Jordi Number/Lot Number

3. 13158 Lot 3436364
4. 13159 Lot 3405405
5. 13160 Lot 3405460
6. 13161 Lot 3422128
7. 13162 Lot 3398135
8. 13163 Lot 3405474

Explant Samples

Jordi Number/Patient Name

1. 13400 Oiler, Jennell
2. 13401 Simpson, Cynthia Ann
3. 13402 Valentino, Gloria
4. 13403 Herman, Sheryl
5. 13404 Phillips, Amy Nicole
6. 13405 Smith, Eva
7. 13406 Wilson, Virginia
8. 13407 Dowden, Ann Marie
9. 13408 Johnston Williams, Shari
10. 13409 Sharp, Jaqueline D.
11. 13410 Ioannov, Stella

[102] ETH.MESH.02219202 - Material Specification for TVT Prolene Polypropylene Mesh Roll Stock
[103] ETH.MESH.09479067 - TVT PROLENE Polypropylene Mesh Rool Stock Appendix II Digital Photograph of 050166
[104] ETH.MESH.01816988 – Mesh Timeline
[105] ETH.MESH.01816988 – Mesh Timeline

12. 13411 McNamara, Eve
13. 13412 Thomas, Theresa
14. 13413 Pankey, Tina
15. 13414 Keller, Linda
16. 13415 Harden, Terri L
17. 13416 Phyllis, Long
18. 13417 Garcia, Alma L
19. 13418 Bonee, Dorothy Sara
20. 13419 Robinson, Tasha R.
21. 13420 Gomez, Flor
22. 13421 Shaw, Ava
23. 13674 Lewis, Carolyn
24. 13675 Batiste, Linda

B. Test Results

A summary of the individual test results from 24 TVT and TVT-O explants is provided below. All accompanying data, including spectra, have been included in the data section of this report and attached as Exhibits "H-M".

Sample Storage

Samples were stored in a temperature controlled (25°C) storage room when not in immediate use. This room was locked and was accessible only to authorized personnel.

Sample Preparation

Control Samples

Control samples were received for analysis in sealed packaging. An example is shown in **Figure 84**. Each sample was then photographed and logged into a database system which assigns an auto-generated sample identification number (Jordi Sample Number as listed in **Table 1**). The packaging was opened and the device was removed. The device consisted of a white plastic handle with a plastic coated metal tool. Attached to the plastic coated metal tool was a fiber mesh inside of a plastic sleeve. The plastic sleeve was removed and the fiber mesh was collected for analysis. For the remainder of this report, all designations regarding the sample are intended to refer to the ***fiber mesh***, as no other portion of the samples was analyzed. Individual test procedures require the use of specific sample preparation techniques. The summary of results for each method indicates how the samples were prepared for that analysis. Analyses performed on the fiber mesh taken from the control samples are summarized in **Table 12** for each sample.

Control Experiment

The control samples were also used as part of a control experiment designed to provide an indication as to the effects of formalin storage. Formalin was used as the storage solvent for transport of the explant samples following surgery prior to their delivery to Jordi Labs. To

that end, a sample of each control material (~100 mg) was placed in formalin (90 ml) and heated at 60°C for 48 hours. In my experience, this temperature would be expected to provide an accelerated rate of aging and is consistent with other published methods for this purpose.[106,107] Following aging, these samples were analyzed in a fashion similar to the explant samples to provide an indication whether or not formalin storage had affected the samples. These samples are referred to as "formalin treated" samples throughout the remainder of this report.

Table 12
Control Samples - Analysis Chart

Sample Lot Number	OM	SEM	SEM EDX	FTIR Micro	DSC	GPC HT	QTOF LCMS	PYMS
3436364	X, F	X, F	X, F		X	X, F	X	X
3405405	X, F	X, F			X	X, F	X, F	X
3405460	X, F	X, F			X	X, F	X	X
3422128	X, F	X, F	F	X	X, F	X, F	X, F	X
3398135	X, F	X, F			X	X, F	X	X
3405474	X, F	X, F			X	X, F	X	X

X indicates that this test was performed on the control sample
F indicates that this test was performed on the control sample following accelerated aging in formalin.

[106] ASTM D3045: http://www.astm.org/Standards/D3045.htm
[107] Inoue, M. (1961), *J. Polym. Sci.*, 55: 443–450.

Figure 84: Example of sample preparation process and sampling location for control samples for Control sample Lot# 3405460. Left (sample as received exterior packaging), right (sample as received interior packaging).

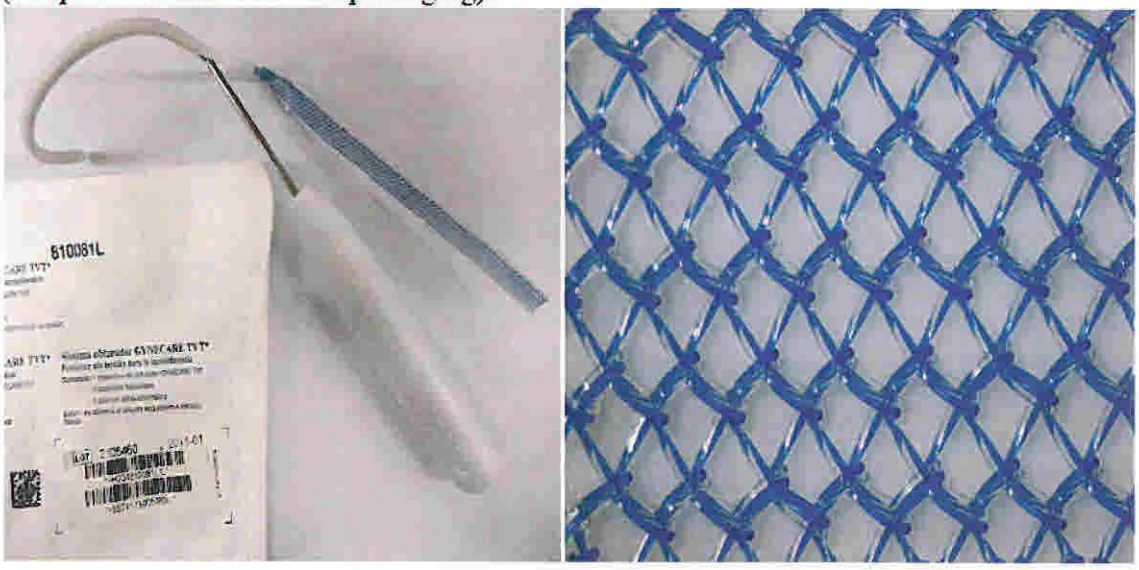

Figure 84 Continued: Example of sample preparation process and sampling location for control samples for Control sample Lot# 3405460. Left (sample device removed from interior packaging), right (fiber mesh used for analysis)

Explant Samples

The explant samples were received for analysis in sealed containers which contained formalin. Each sample was then photographed and logged into a database system which assigns an auto-generated sample identification number (Jordi Sample Number as shown in **Table 13**). The containers were opened and the samples were initially separated into two portions of approximately equal length. The first half was returned to Steelgate. The second half was then sectioned again to prepare an approximately .5cm x .5cm portion which was returned to a legal representative. The remaining portion was used for analysis at Jordi Labs.

The preparation of each sample included weighing the original sample following blotting with a kim wipe to remove excess formalin. The samples were then sectioned for OM, SEM, SEM-EDX and FTIR-microscopy analysis. These tests are non-destructive and thus it was possible to analyze a single portion of sample by all of these methods. The samples were sectioned using a fresh disposable scalpel to cut off a portion of the explant which was approximately 2-3mm in length. A small amount of tissue was carefully removed using forceps to uncover the fibers present underneath. The minimum amount of tissue required was removed so as to avoid disturbing the fibers. In all ways, care was taken to minimize any impact on the fibers. An example of the portion analyzed by OM, SEM, SEM-EDX and FTIR-microscopy is shown in **Figure 85**.

The fiber mesh was then freed from the tissue matrix using forceps. The fibers and tissue were then collected in separate vials and weights of each were recorded. OM images of each fraction were then taken. **Figure 85** shows an image of the fibers and tissue following separation. The fibers were placed under reduced pressure for one hour to ensure complete removal of the traces of formalin. For the remainder of this report, all designations regarding the sample are intended to refer to the ***Fiber Mesh (Figure 85 bottom left)*** or to the ***Fiber Mesh Embedded in Tissue (Figure 85 top right)*** as no other portion of the samples was analyzed. Individual test procedures require the use of specific sample preparation techniques. The summary of results for each method indicates how the samples were prepared for that analysis. **Table 13** summarizes the testing which was performed on each explant sample.

The sample preparation methods utilized by Jordi Labs were selected to protect the integrity and scientific reliability of the results obtained, and were necessary so that we could understand if the cracks were evidence of degraded polypropylene and/or biofilm. The methods applied represent the optimum way to prepare the samples given the totality of the tests which were to be performed, the limited sample quantity and the potential for testing artifacts following chemical treatments on the explants. It is a general principle in investigative chemistry and forensic science that the minimum amount of sample preparation required is preferred. The reason this is true is that all sample preparation no matter how carefully performed increases the risk of contamination, loss or otherwise adulterating the sample. Therefore, we believe to a reasonable degree of scientific certainty that the sample cleaning method utilized in the Jordi Analysis is superior to the use of any chemicals to dissolve the tissue.

Table 13
Explant Sample - Analysis Chart

Sample Ident.	Weight Fibers	OM	SEM	SEM EDX	DSC	FTIR Micros.	GPC HT	QTOF LCMS	PYMS
13400	12.536	T, FM	T	T	FM	FM	FM	FM	FM
13401	18.464	T, FM	T		FM			FM	FM
13402	22.482	T, FM	T		FM		FM	FM	FM
13403	2.128	T, FM	T	T					FM
13404	4.292	T, FM	T				FM		
13405	7.302	T, FM	T			FM		FM	FM
13406	1.428	T, FM	T						
13407	14.512	T, FM	T		FM		FM	FM	FM
13408	6.322	T, FM	T	T	FM			FM	FM
13409	8.984	T, FM	T	T	FM		FM	FM	FM
13410	5.324	T, FM	T				FM	FM	
13411	34.68	T, FM	T		FM		FM	FM	FM
13412	7.06	T, FM	T			FM	FM	FM	FM
13413	8.26	T, FM	T			FM	FM	FM	FM
13414	7.162	T, FM	T		FM		FM	FM	FM
13415	11.534	T, FM	T		FM		FM	FM	FM
13416	8.068	T, FM	T		FM		FM	FM	FM
13417	1.772	T, FM	T						
13418	19.45	T, FM	T	T	FM		FM	FM	FM
13419	3.932	T, FM	T		FM				FM
13420	9.044	T, FM	T		FM				FM
13421	8.188	T, FM	T		FM		FM	FM	FM
13674	7.620	T, FM	T	T	FM	FM	FM	FM	FM
13675	5.258	T, FM	T	T	FM	FM	FM	FM	FM

T - indicates that this test was performed on Fiber Mesh Embedded in Tissue
FM - indicates that this test was performed on Fiber Mesh

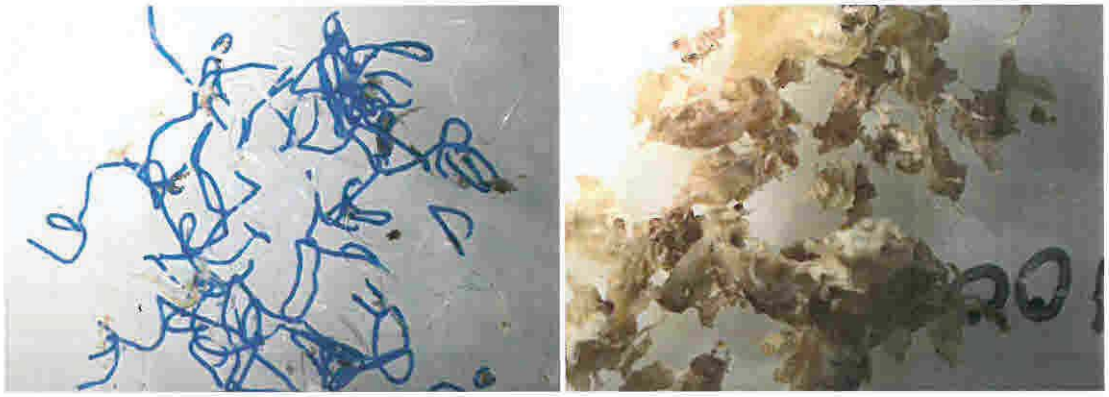

Figure 85: Example explant sample showing the sample preparation process. Top Left (sample as received), Top Right (sample as prepared for OM, SEM, SEM-EDX and FTIR-microscopy), bottom left (fibers removed from tissue matrix), bottom right (tissue matrix after fiber removal)

Observations

It was noted during sample preparation that a readily apparent difference in fiber stiffness existed between the control samples and the explanted fiber mesh. The control samples were observed to be highly flexible and were noted to have flexibility similar to that of fishing line (a typical polypropylene fiber). The explant samples were observed to be much stiffer and to break when bent sufficiently. In contrast, the control samples showed greater flexibility and elasticity and tended to return to their original shape following distortion. When intentionally subjected to strong force, the explant samples were observed to crack completely in some instances and to form two pieces. Similar force applied to the control fibers did not result in cracking.

It is therefore my opinion, to a reasonable degree of scientific certainty, that based upon these observations the mesh hardens, stiffens and becomes markedly less pliable once implanted and subjected to the environmental factors of the tissue in which it was implanted.

SEM and OM

Sample Preparation

Samples were prepared for variable pressure SEM analysis by simply cutting a portion of the sample and removing enough tissue to expose the fiber surface. This was done carefully to avoid direct contact with the fibers. No sputter coating or other sample pretreatment was required due to the use of environmental SEM. The samples were mounted on 12 mm diameter Al stubs that were partially covered with carbon tape. In order to avoid any cracking during mounting, the samples were laid down gently onto the C tape without pressing them on. The samples were analyzed by optical microscopy prior to SEM to show a larger image and to aid in identification of sample features.

Results

Individual SEM and OM images are provided below for each control sample and the explant samples. Additional images are provided for each sample in the data section of this report. **Figure 86-97** show the results for the control samples. **Figure 98-145** show the results for the explant samples. The control samples were observed to show very smooth surfaces with relatively few imperfections. No cracking was observed in the control samples. A very small amount of particulate matter was observed attached to the surface of the control fibers.

In contrast, the explant samples showed three distinct morphologies (textures/shapes). Some portions of the fibers appeared smooth similar to that in the control samples. Other portions showed cracking and pealing of the surface layer. Finally, some regions were consistent with adhesion of a foreign material to the fiber surface. A comparison of this adhered foreign material with the surrounding tissue showed that this material had a consistent morphology with the tissue. **Figure 111** shows a good example of all three textures with each region highlighted for clarity.

The explant samples can be readily grouped into three categories. Two of the samples (13419 and 13421) showed no visible indications of cracking. Four of the samples showed moderate cracking (13401, 13408, 13411 and 13420). The remaining eighteen samples showed extensive cracking. The nature of the cracking in these later samples was often very substantial. **Figure 105, 113, 109,** and **135** are good examples of this. The cracks were observed to occur generally in a direction perpendicular to the fiber draw direction. When cracking became extensive, the cracked material was also observed to begin to peel away from the remainder of the underlying fiber.

Control Experiment

A control experiment was conducted to confirm that the cracking observed was not related to storage of the fibers in formalin. This fluid was used for transport of the specimens following surgery prior to their delivery to Jordi Labs. Following aging of the samples in formalin, the samples were analyzed in a fashion similar to the explant samples. SEM results for all six control lots are shown in the data section, but one example is presented in **Figure 146** and **147**. The surface of the fibers was found to remain smooth. It is my opinion to a reasonable degree of scientific certainty that this supports that the cracking observed in the explants occurred prior to storage of the fibers in formalin.

Scientific Opinion

Based on numerous scientific literature, my knowledge, training and experience, and my examination of the data, it is my opinion to a reasonable degree of scientific certainty that the SEM results are consistent with cracking of the polypropylene fiber. The images support that the polypropylene itself is cracking as in **Figure 117** and **145** where the fiber extrusion lines can be seen to extend through the cracked region. The fiber cracking process appears to be generally localized to the surface layers of the fibers; however, in some explant samples, the

XIII. COMPENSATION

I am compensated for investigation, study and consultation in this case at the rate of $350.00 per hour.

This 7th day of July, 2014

Howard Jordi, Ph.D.